K073346

510(k) Summary
as required by 807.92

DEC 19 2007

1. Company Identification
EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent
Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission
• • November 27, 2007

4. Device Trade name
Color LCD Monitor, FlexScan MX300W

5. Common/Usual Name
Image display system, medical image workstation, image monitor/display, and others

6. Classification Number
Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	Color LCD Monitor
Model Name	:	RadiForce R31
510(k) No.	:	K052344

8. Description of Device
FlexScan MX300W is a 76cm (29.8") Color LCD display for medical image viewing and digital images viewing. MX300W displays high-definitions medical imaging.

9. Intended Use
FlexScan MX300W is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. FlexScan MX300W does not support the display of mammography images for diagnosis.

10. Technological Characteristics
FlexScan MX300W is substantially equivalent to RadiForce R31 (K052344). The panel size became big with 76cm (29.8") from 53cm (20.8"). MX300W employs the maximum resolution values same as that of R31. Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. And the brightness improved. Comparison table of the principal characteristics of 2 devices is shown in the Appendix 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2007

Mr. Hiroaki Hashimoto
Manager
EIZO NANAO CORPORATION
Engineering Management Section
153 Shimokashiwano-cho
Hakusan, Ishikawa-ken 924-8566
JAPAN

Re: K073340
Trade/Device Name: Color LCD Monitor, FlexScan MX300W
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 22, 2007
Received: November 28, 2007

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K073340

Device Name : Color LCD Monitor, FlexScan MX300W

Indications for Use:

FlexScan MX300W is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. FlexScan MX300W does not support the display of mammography images for diagnosis.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073340